

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Patent Application of)	
Peter GLUCKMAN et al.)	Group Art Unit: 1654
Application No.: 10/606,745)	Examiner: Jeffrey E. Russel
Filed: June 27, 2003)	Confirmation No.: 5345
For: IGF-1 TO IMPROVE NEURAL OUTCOME)	

SUBSTITUTE REISSUE DECLARATION

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

We, Peter Gluckman, residing at 78 Lucerne Road, Remuera, Auckland, 5, New Zealand (citizen of New Zealand), and Karoly Nikolics, residing at 6245 Lakemead Way, Emerald Hills, California 94062 (citizen of Hungary and the United States), do hereby declare and state that:

- (1) We reside at the above-identified respective residences and are the original first and joint inventors of the invention described in U.S. Patent No. 5,714,460, issued February 3, 1998 ("the '460 patent"), and described and claimed in the application for a reissue application.
- (2) We have reviewed and understand the contents of the above-identified reissue application for reissue patent, including Claims 16-26, 28-38, and 64-65.
- (3) We acknowledge the duty to disclose information material to the examination of this application in accordance with Title 37, Code of Federal Regulation § 1.56(a).
- (4) The '460 patent is wholly or partly inoperative or invalid by reasons of the patentees claiming more or less than they had the right to claim in the patent by reason of

Claim 1 of the '460 patent being susceptible to the broad interpretation that the method treats neural damage to any neural cell, rather than being limited to treatment of glia and non-cholinergic cells.

(5) Claim 1 of the '460 patent, as issued, reads as follows:

A method of treating neural damage suffered
after a CNS insult affecting glia or other non-
cholinergic cells in a mammal, comprising
administering to the central nervous system of said
mammal an effective amount of IGF-1 and/or a
biologically active analogue of IGF-1.

(6) In a Decision in Interference 104,553 involving the '460 patent, the Board stated that "[t]he Gluckman claims making up the count require an 'insult' affecting glia or non-cholinergic cells', but are not limited to conditions in which glia and other non-cholinergic cell loss predominates." (Decision on Motions, p. 21)

(7) The Board also stated in the Decision that "[t]he broadest reasonable construction of Gluckman's 460 claim 1 and 373 claim 1 is that the treatment must be for a CNS insult 'affecting' glia or other non-cholinergic cells, but may also affect cholinergic neurons." (Decision on Motions, p. 40)

(8) In light of the broad construction of Claim 1 of the '460 patent, the Board found it unpatentable over prior art.

(9) Claims 16-26 and 28-38, now submitted in the present reissue application, are directed specifically to "treating glial cells damaged from CNS injury, wherein said CNS injury predominantly affect glia." Claims 64 and 65, now submitted in the present reissue application, are directed specifically to treating non-cholinergic cells damaged from CNS injury, wherein the CNS injury is an injury to the hippocampus.

(10) We agree that all errors which are being corrected in the reissue application up to the time of filing the oath/declaration arose without any deceptive intention on the part of the application.

(11) Applicants claim priority of New Zealand Application 239211 filed on August 1, 1991.

(12) We hereby appoint the attorneys of Bingham McCutchen (Customer No. 23639) with full power of substitution and revocation to prosecute this application and to transact all business in the Patent and Trademark Office in connection therewith.

All correspondence may be directed to:

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(13) We hereby declare that all statements made herein are believed to be true and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code and that such willful, false statements may jeopardize the validity of the application and any patent issued or reissued thereon.

Full name of first inventor Peter Gluckman

Inventor's signature _____ Date _____

Residence _____

Full name of second inventor Karoly Nikolics

Inventor's signature _____ Date _____

Residence _____